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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/453,726	12/02/1999	DAVID M READ	52951-USA-7A	2987

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JEFFREY J HOHENSHELL
OFFICE OF IINTELLECTUAL PROPERTY COUNSEL
3M INNOVATIVE PROPERTIES COMPANY
P O BOX 33427
ST PAUL, MN 551333427

EXAMINER	
CHORBAJI, MONZER R	
ART UNIT	**PAPER NUMBER**
1744	12

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/453,726	READ, DAVID M
	Examiner	Art Unit
	MONZER R CHORBAJI	1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

This final office action is in response to the amendment received on 12/26/2002

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1, line 13; applicant added the limitation "wherein the indicator composition does not include a halogen source". Such a limitation was not disclosed in the originally filled application. The same applies to claim 10, line 14.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-3, 5-6, 9-13, 15-16, 19-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Ignacio et al (U.S.P.N. 6,287,518).

With respect to claims 1, 10-11, Ignacio discloses a hydrogen peroxide sterilization indicator (col.5, lines 53-55) composition including a binder (col.3, lines 40-41) disposed on a substrate (col.4, lines 14-15) such that the composition includes malachite green oxalate (col.6, lines 38-39). In addition, Ignacio teaches colorants that do not change color upon contact with hydrogen peroxide vapor can be used as well (col.3, lines 54-56). Furthermore, Ignacio discloses a method of monitoring a hydrogen peroxide sterilization process (col.2, lines 60-61 and col.5, lines 53-55) that exposes an article and the indicator to hydrogen peroxide vapor (col.9, lines 53-62).

The limitations of claims 2-3, 12-13, and 21, have been addressed above with regard to claims 1 and 10.

The limitations of claims 6 and 16 have been addressed above with regard to claim 10.

With respect to claims 5 and 15, Ignacio's composition includes thionine (col.6, line 37). Note that thionine and thionin are synonyms.

With respect to claims 9, 19, and 20, Ignacio's indicator includes a polyester film substrate (col.3, line 65) and a shellac binder (col.3, line 41).

With respect to claim 22, Ignacio's method includes exposing the article and the indicator to hydrogen peroxide vapor (col.2, lines 60-61, col.5, lines 53-55 and col.9,

lines 53-62) such that the vapor must inherently be applied under certain temperature and pressure ranges in order to achieve sterilization.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (U.S.P.N. 6,287,518) in view of Malchesky et al (U.S.P.N. 5,518,927).

The teachings of Ignacio have previously been set forth with respect to claims 1-3, 5-6, 9-13, 15-16, 19-22. With respect to claims 4 and 14, Ignacio fails to disclose such colorants. Malchesky's sterilization indicator changes colors during such processes (col.2, lines 4-7 and col.3, lines 24-26) teach the use of safranine (col.3, line 56). Note that safranine is a synonym to methylene violet. Furthermore, Malchesky's indicator is used in vapor sterilization cycles (col.3, lines 30-32). Even though Malchesky's indicator is used for peracetic acid cycles, Malchesky teaches that the

indicator can be used for any type of vaporous sterilant (col.3, lines 30-32). Since vaporous hydrogen peroxide is a well-known sterilant, then Malchesky's indicator can be used with such a sterilant. It would have been obvious to one having ordinary skill in the art to modify the composition of Ignacio to include safranine, which can be used with various types of sterilants (Malchesky, col.3, lines 30-32).

9. Claims 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (U.S.P.N. 6,287,518) in view of Bealing et al (U.S.P.N. 5,990,199).

The teachings of Ignacio have previously been set forth with respect to claims 1-3, 5-6, 9-13, 15-16, 19-22. With respect to claims 7 and 17, Ignacio fails to explicitly disclose specific examples of colorants that do not change color upon contact with hydrogen peroxide vapor. Bealing's vapor phase hydrogen peroxide indicator (col.4, lines 15-18) includes Janus green B dye (col.6, line 26). It would have been obvious to one having ordinary skill in the art to modify the composition of Ignacio to include Janus green B dye to determine the effectiveness of sterilization processes for vapor phase hydrogen peroxide (Bealing, col.4, lines 7-9).

10. Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (U.S.P.N. 6,287,518) in view of Bealing et al (U.S.P.N. 5,990,199) and further in view of Barrett (U.S.P.N. 5,955,025).

The teachings of Ignacio have previously been set forth with respect to claims 1-3, 5-6, 9-13, 15-16, 19-22. With respect to claims 8 and 18, Ignacio fails to explicitly disclose such limitations. With regard to claims 8 and 18, Bealing discloses various classes of colorant acid blue can be used (col.6, lines 36-38). For example, Bealing

uses Acid blue #7 or Acid blue #20. Alkali blue 6B is also known as Acid blue #119. Since Bealing provides only examples (col.6, lines 32-38) of using various classes of the colorant acid blue, choosing a different class of acid blue (i.e., Acid blue #119) is not non-obvious and is well within the scope of the artisan. Furthermore, as explained above Bealing discloses the use of Janus green B, however, fails to specifically disclose the use of Quinacridone red 19. Barrett discloses the use of Quinacridone red (col.4, table). Barrett does not disclose the use to Quinacridone red 19. However, the significance of "19" is not understood by the examiner. It would have been obvious to one having ordinary skill in the art to modify the composition of Ignacio to include any of the available and known class or classes of acid blue dyes including acid blue #119 and Quinacridone red to indicate when a particular article has been subjected specifically to vaporous hydrogen peroxide for sterilization (Barrett, col.2, lines 58-61).

Response to Arguments

11. On page 4 of the response, applicant argues, "As applicant's claims recite an indicator composition that does not require a halogen source to provide a change in color in the presence of a sterilant, such as hydrogen peroxide". Such a limitation added to claims 1 and 10 was not disclosed in the original application resulting in new matter issues.

On page 4 of the response, applicant argues, "Methylene violet RR (C.I. 50205) is not recited in applicants claims. Applicant's claims include Methylene violet (C.I. 52041), which is a thiazine dye and is structurally different from safranine". On page 18,

table 2 does not contain a color indicator number. How would one know with so many methylene violet compounds that applicant intended methylene violet (C.I. 52041)?

On page 5 of the response, applicant argues, "Applicant, therefore, asserts that not only does the disclosure of Janus green B in Bealing et al. in combination with Ignacio et al. not provide that which is missing from Ignacio et al., the disclosure of Bealing et al. teaches away from Applicant's claims". Janus green B in Bealing et al was added based on Ignacio et al teaching of addition of colorants that do not change color during the sterilization process (col.7, lines 17-19). Janus green B is a component disclosed in both the claims and Bealing et al, such that, they teach of a dual function of such a component (i.e., Janus green B is capable of changing or not changing color). As a result, depending on the intended use of Janus green B, adding such a component to Ignacio's composition is obvious as disclosed by Ignacio et al.

On page 5 of the response, applicant argues, "Applicant submits that one cannot simply substitute a colorant disclosed in Bealing et al. into the disclosure of Ignacio et al. and reasonably expect to successfully provide a sterilization indicator". Ignacio et al teaches that the composition includes both types of colorants that do change color (i.e., halogenated) and others that do not change color (i.e., not halogenated). Both the claims and Bealing et al show that Janus green B is capable of changing or not changing colors depending on the intended application. Such that Ignacio et al would lead someone to add a dual function component such as Janus green B disclosed in Bealing et al to provide a composition that contains both types of colorants that do or do not change color.

On page 5 of the response, applicant argues, "Furthermore, Bealing et al. do not disclose Alkali blue 6B (acid blue 119)". Bealing et al discloses various classes of colorant acid blue can be used (col.6, lines 36-38). For example, Bealing uses Acid blue #7 or Acid blue #20. Alkali blue 6B is also known as Acid blue #119. Since Bealing provides only examples (col.6, lines 32-38) of using various classes of the colorant acid blue, choosing a different class of acid blue (i.e., Acid blue #119) is not non-obvious and is well within the scope of the artisan.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-7719 for After Final communications.

16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji MRC
Patent Examiner
AU 1744
March 19, 2003